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**Toellner**

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(54) **SYSTEM FOR INTRODUCING A PUMP**

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(58) **Field of Classification Search**
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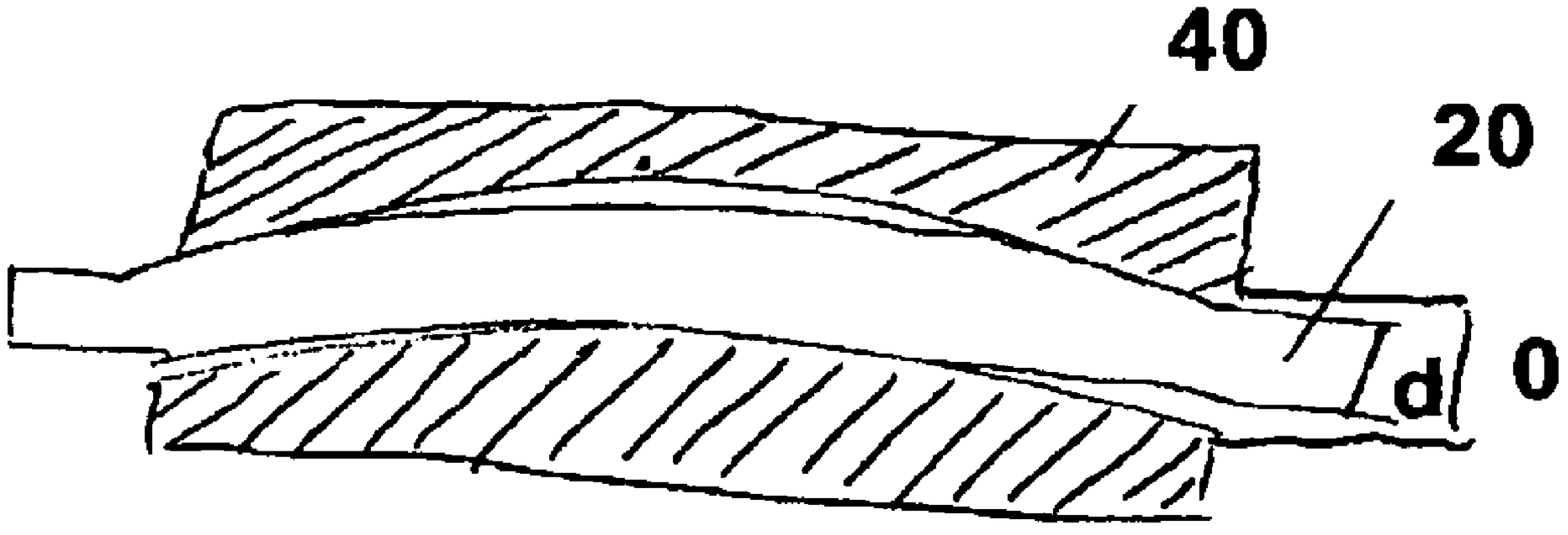
(57) **ABSTRACT**

The invention resides in the field of introducing fluid pumps into a lumen and relates to a system for introducing a pump into a lumen which comprises a first sheath and a pump to be introduced into the first sheath, or a system which has a pump with a distal pump unit and a shaft catheter which emerges proximally to the pump unit. According to the invention one or two sheaths are used, the distal pump unit being pulled firstly into the distal end of one sheath, in order to avoid damage to a shaft catheter. Subsequently, the sheath receiving the pump unit is transferred into a further sheath or a receiving lumen.

**11 Claims, 7 Drawing Sheets**



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(58) **Field of Classification Search**

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See application file for complete search history.

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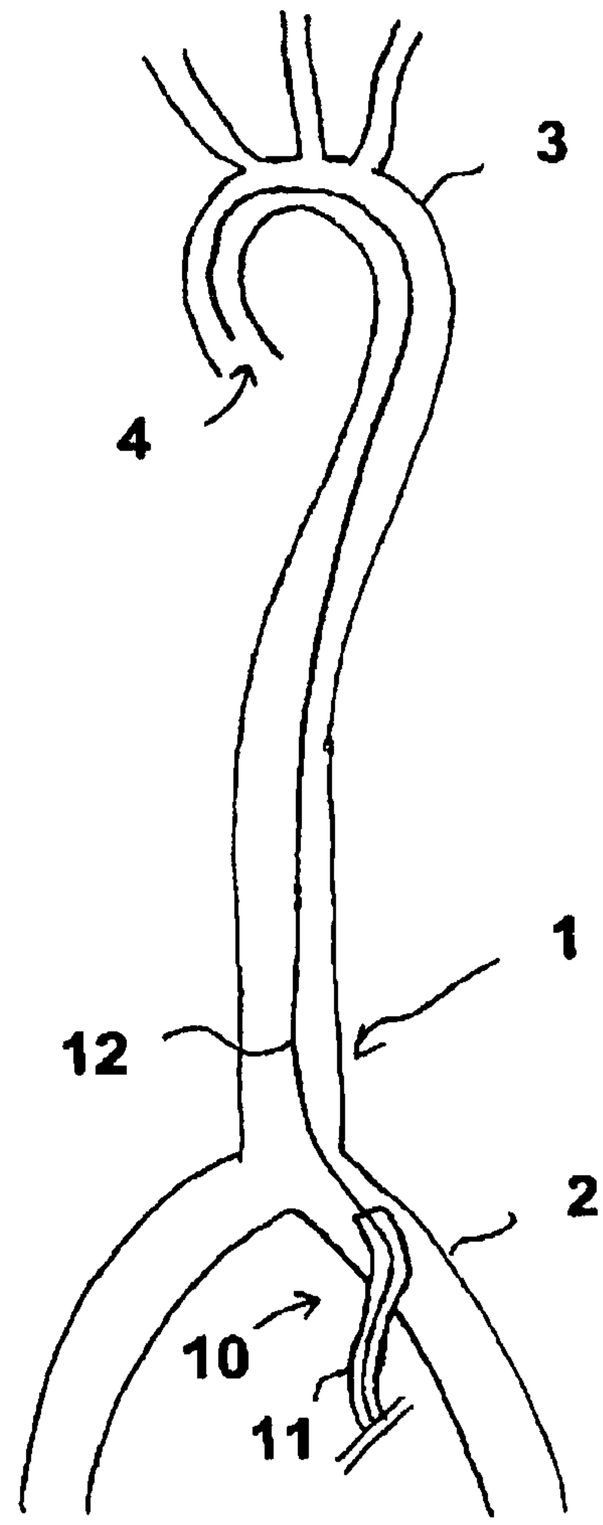
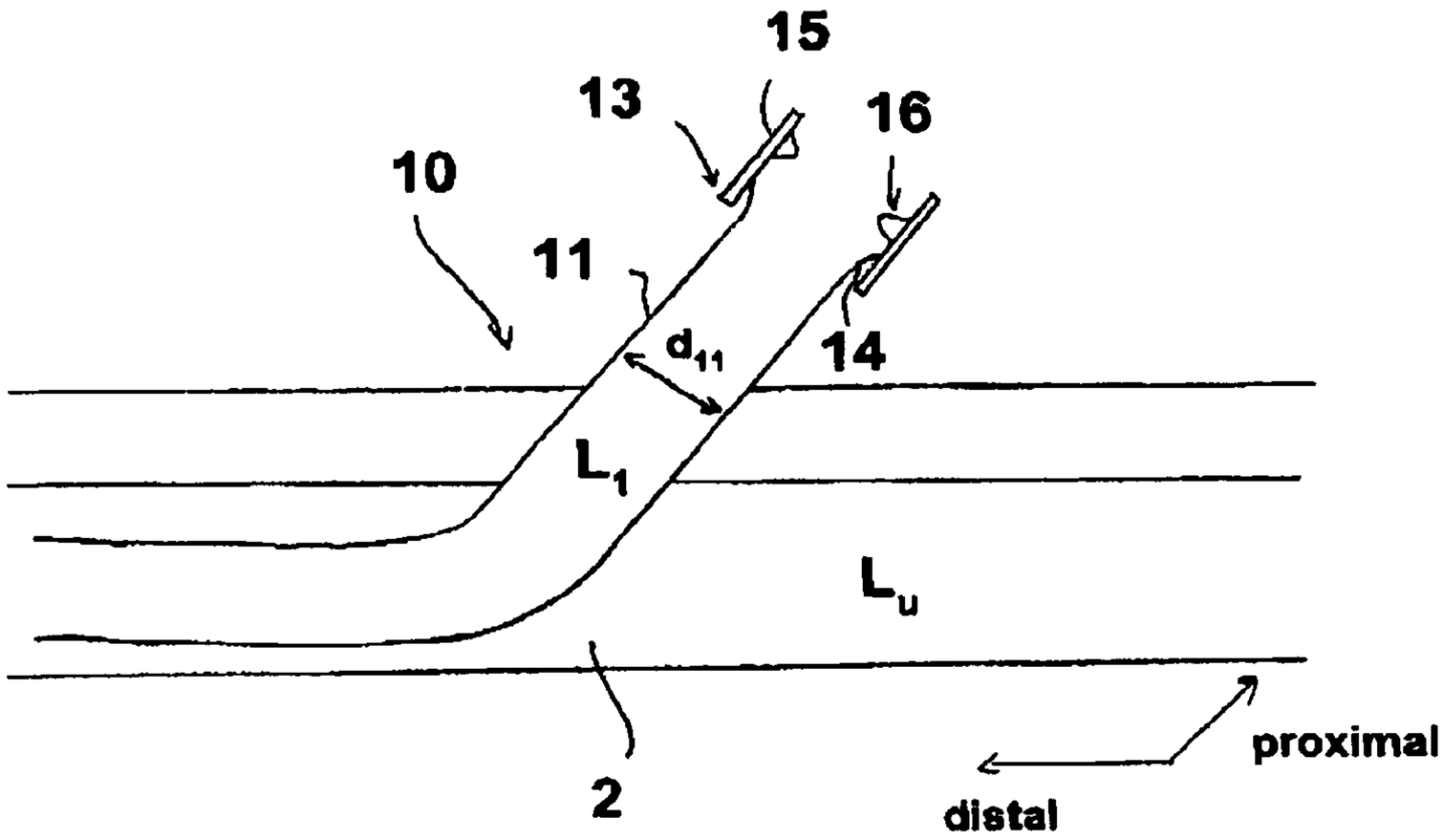



Fig. 1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11
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14
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$L_u$
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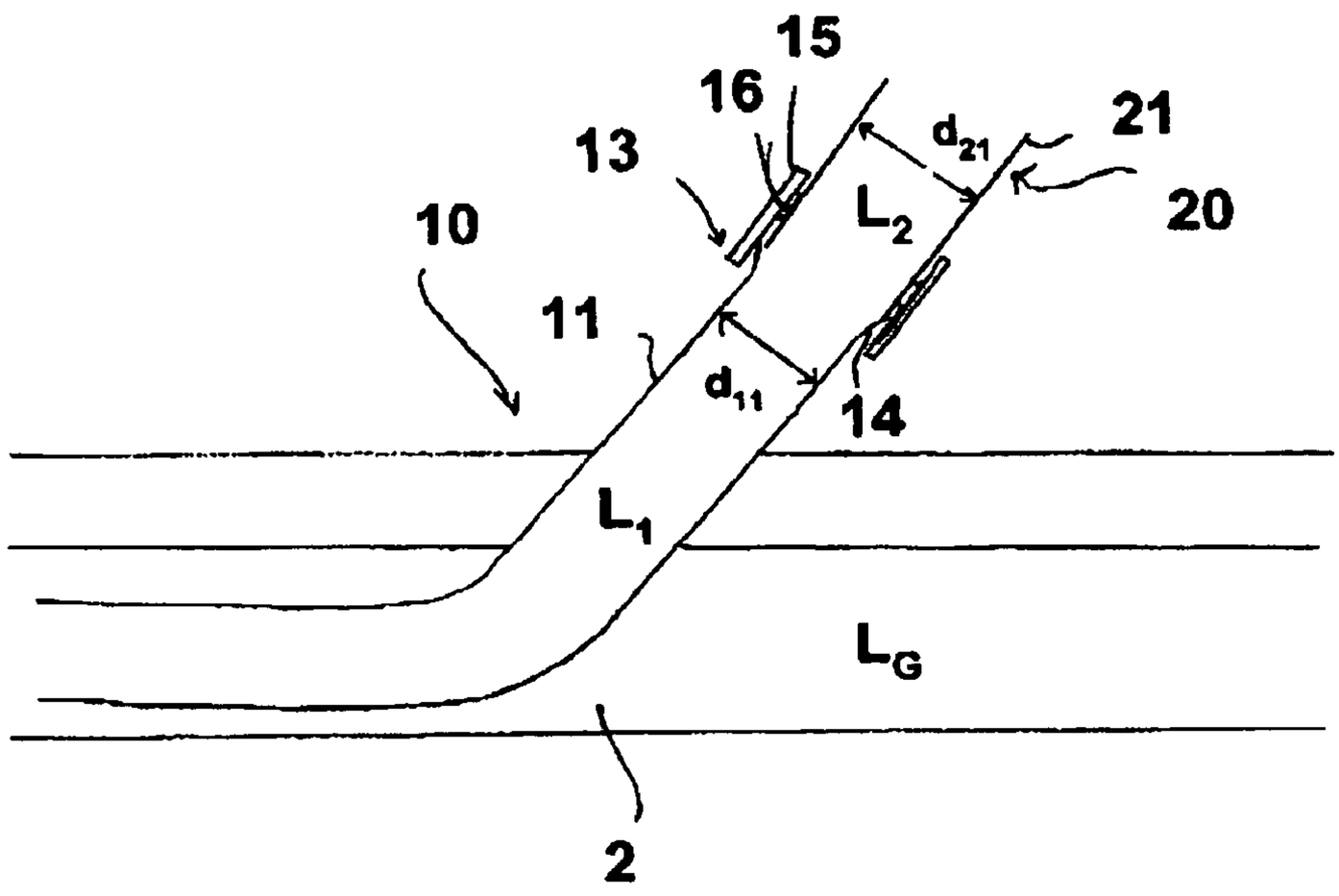
proximal
distal

Fig. 2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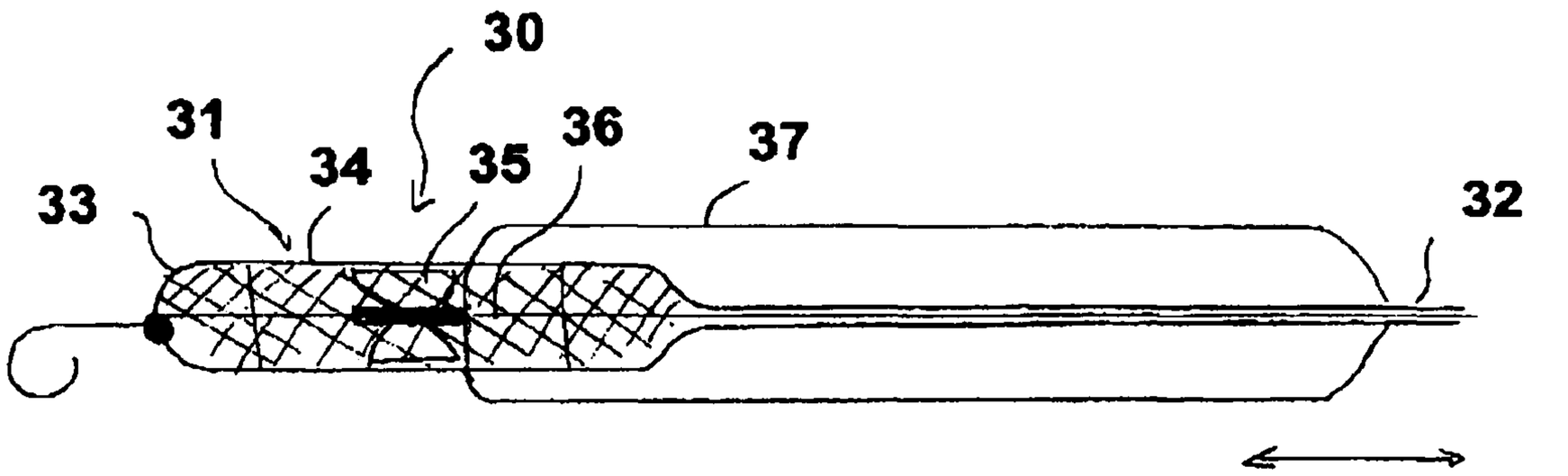
2

Fig. 3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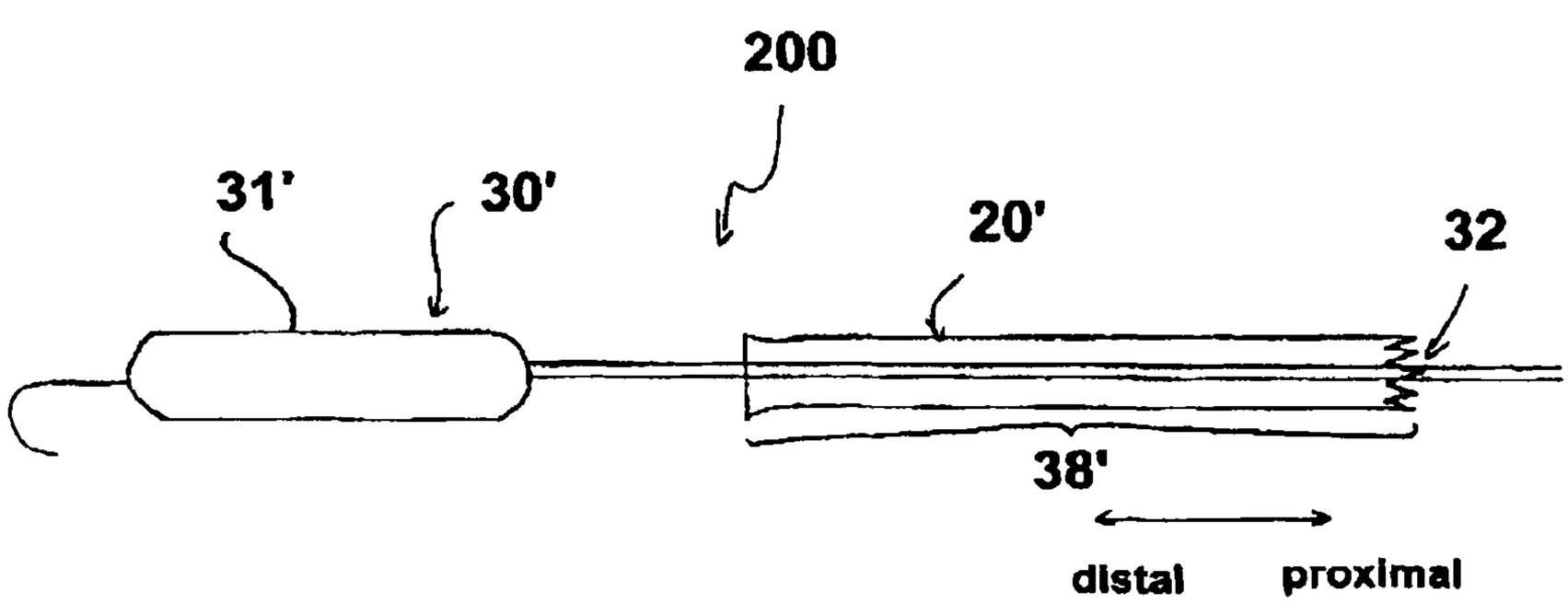
distal
proximal

Fig. 4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20'
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Fig. 5

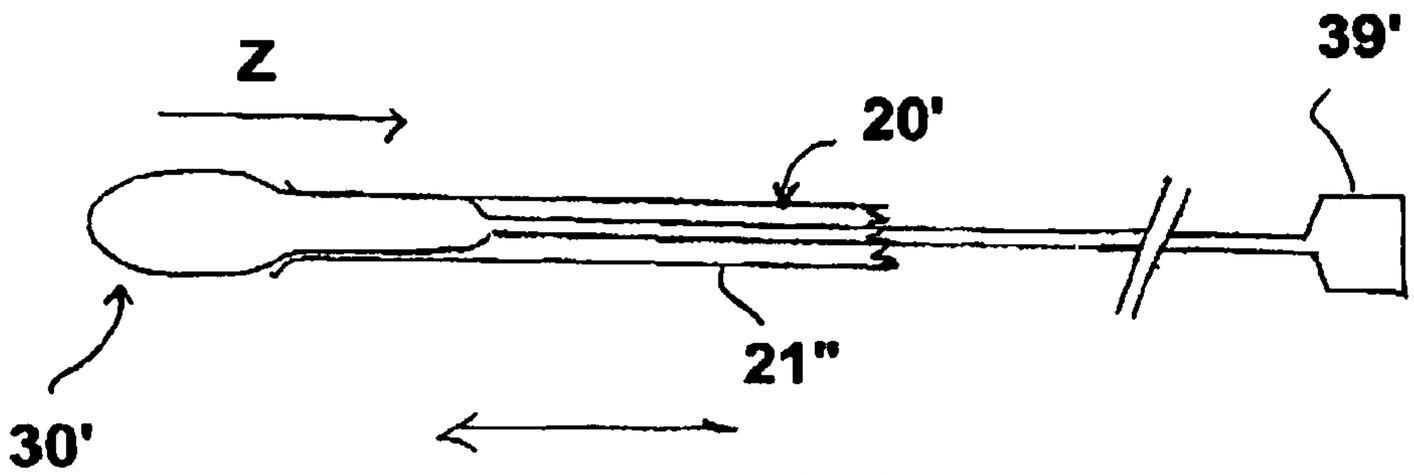


Fig. 6

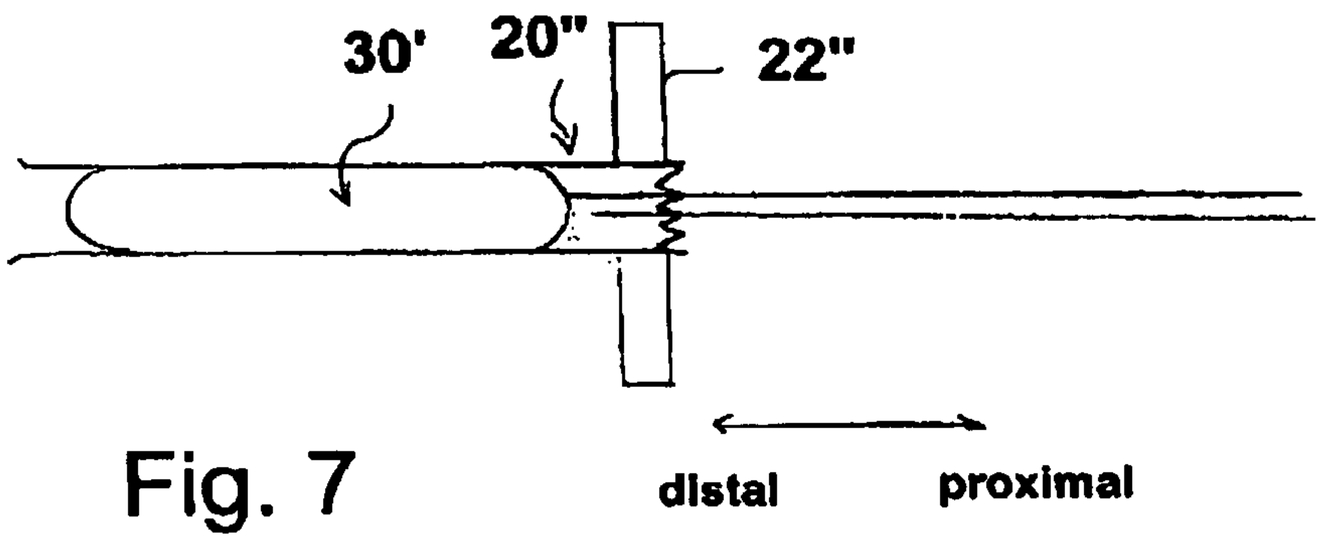


Fig. 7

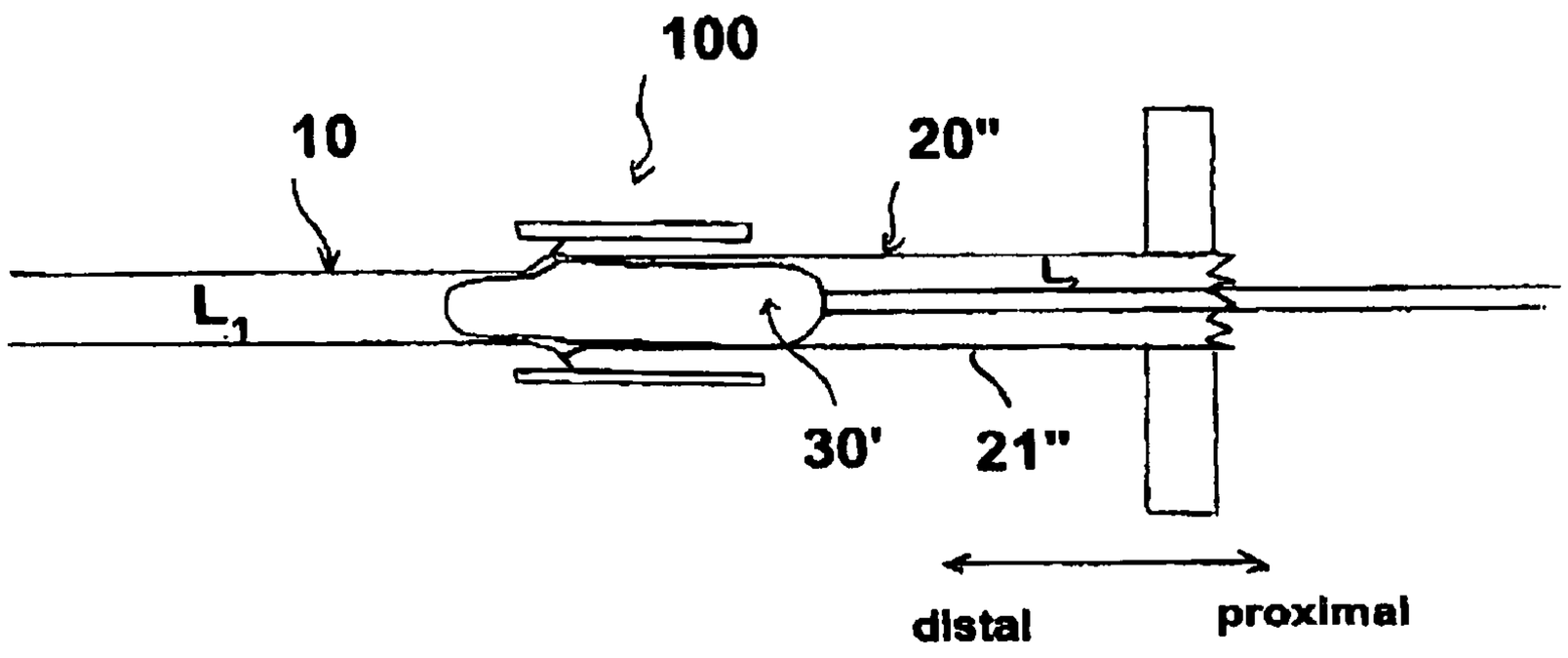


Fig. 8

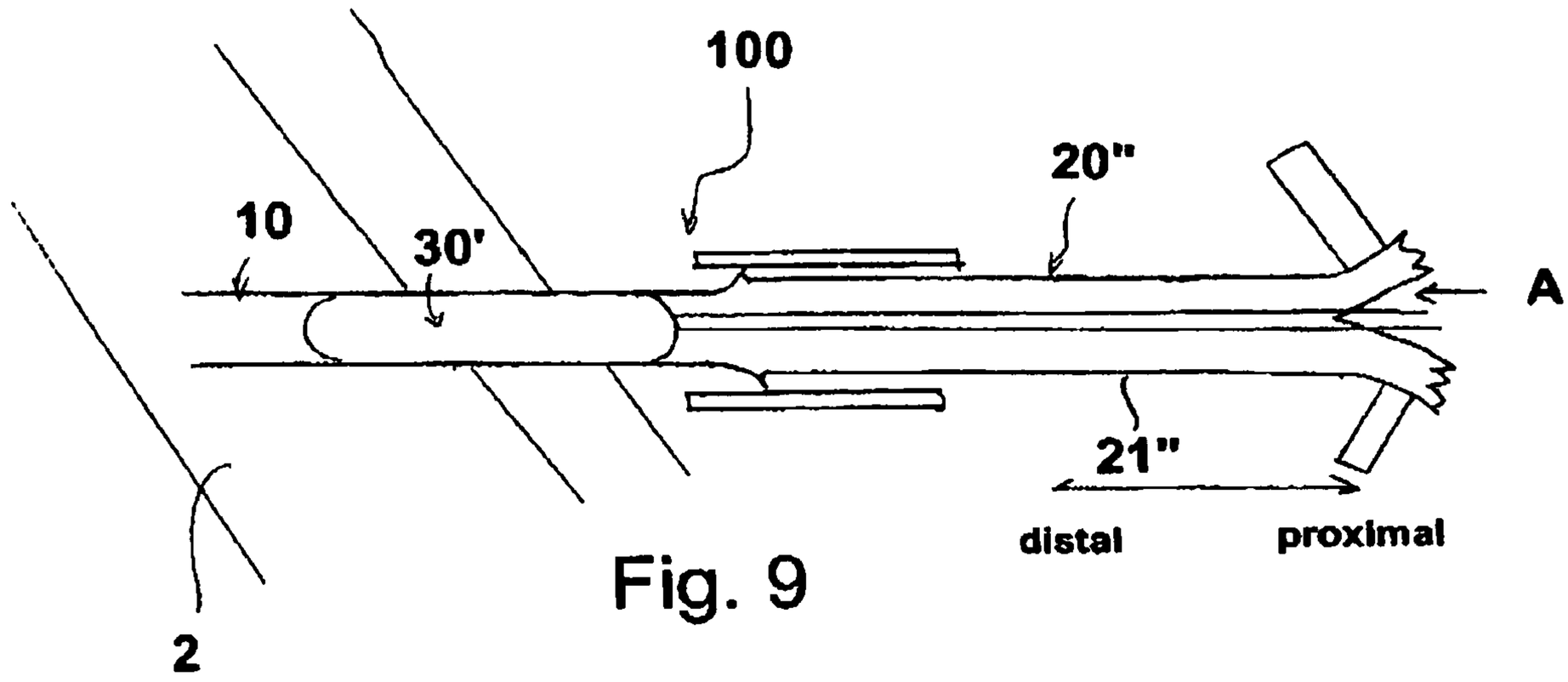


Fig. 9

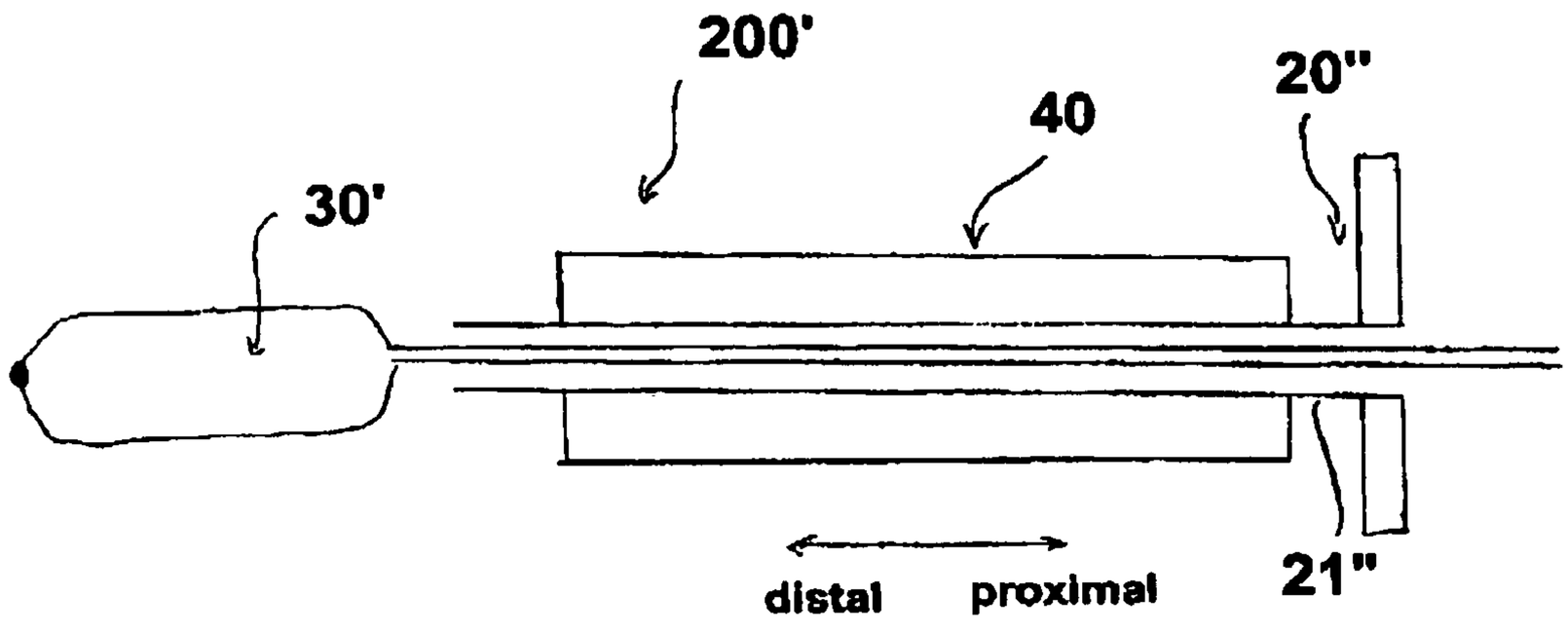


Fig. 10

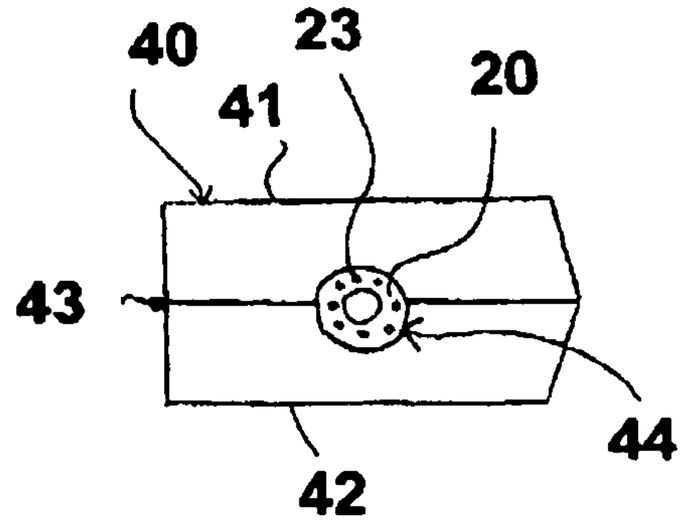


Fig. 11

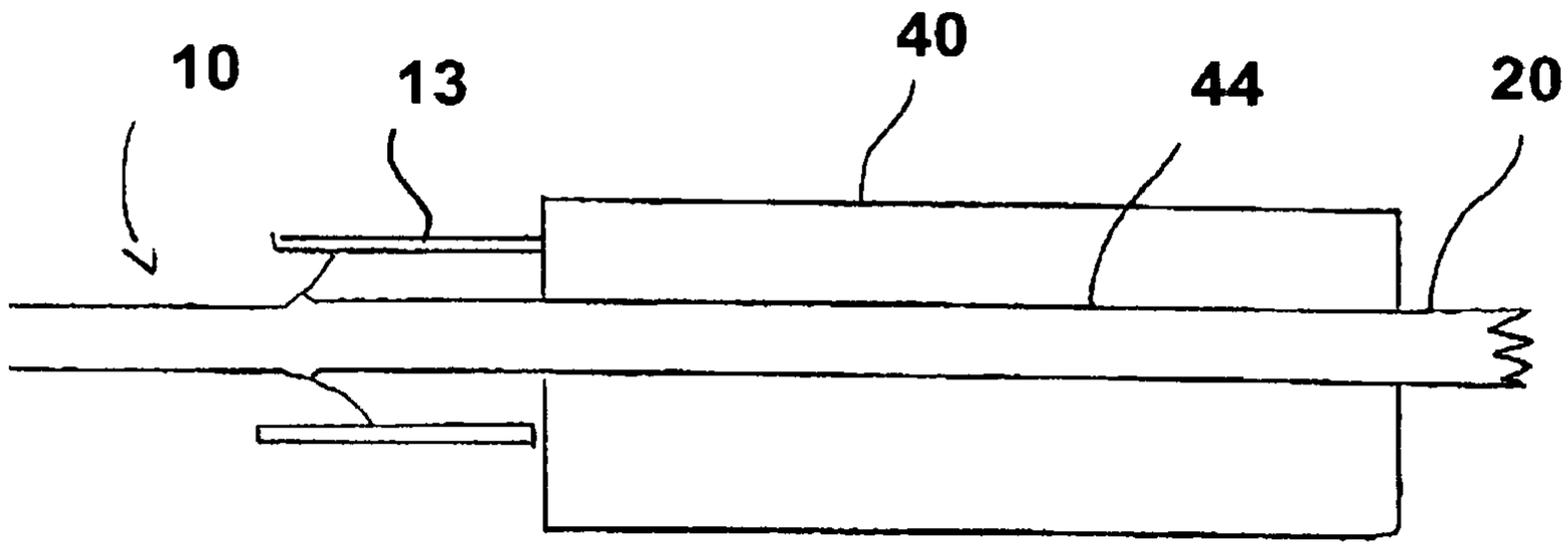


Fig. 12

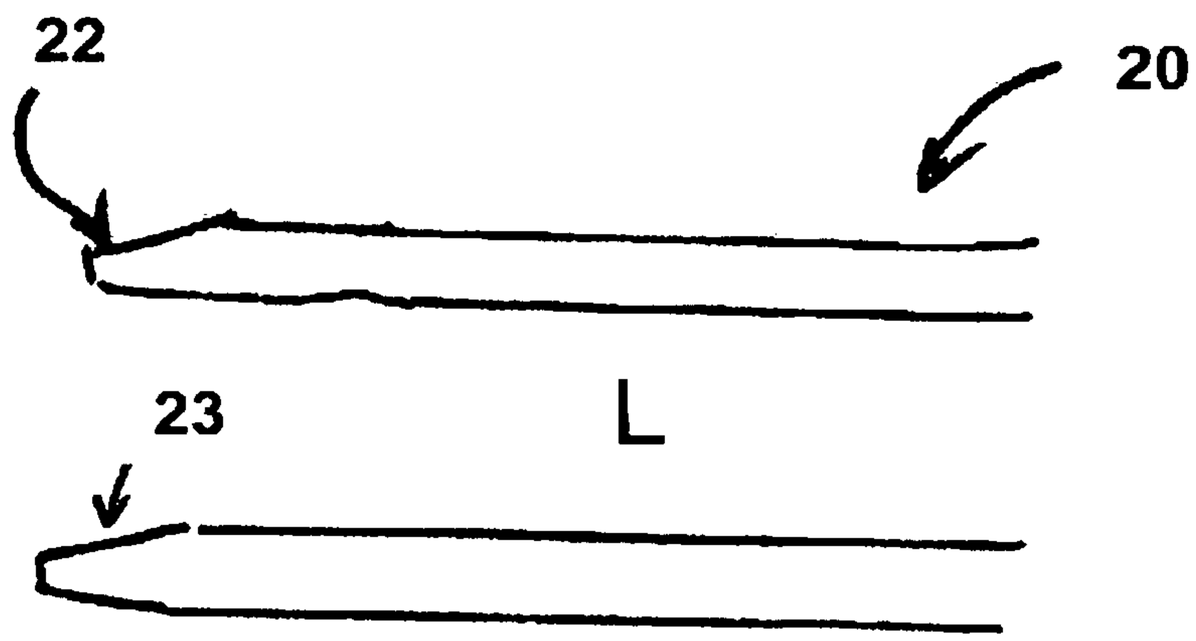


Fig. 13a

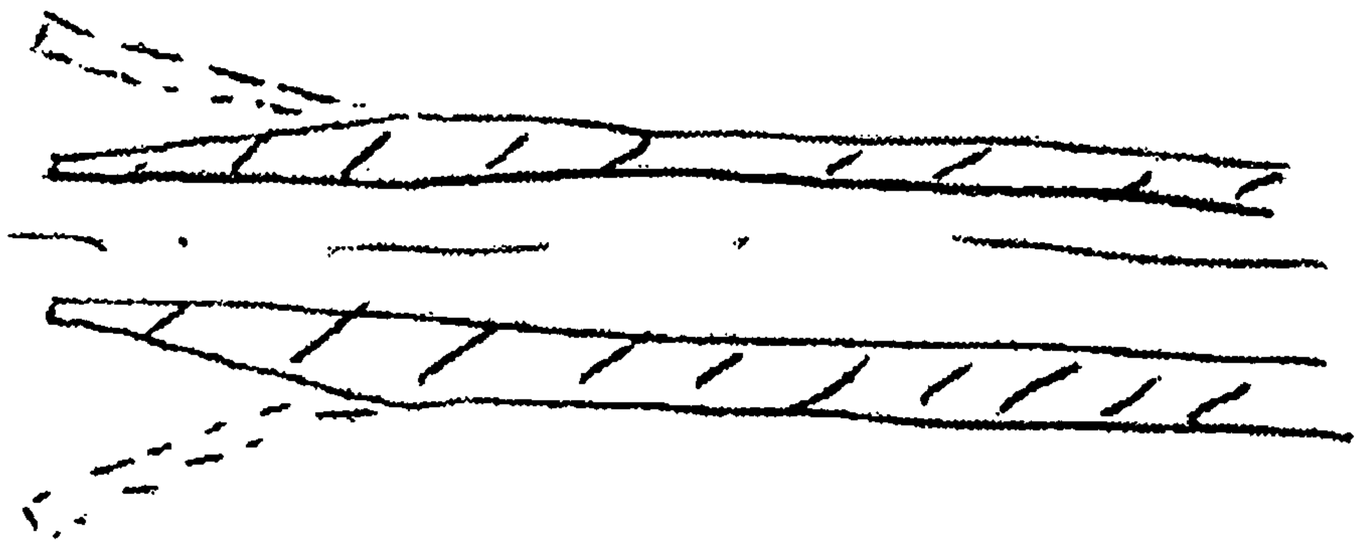

Fig. 13b

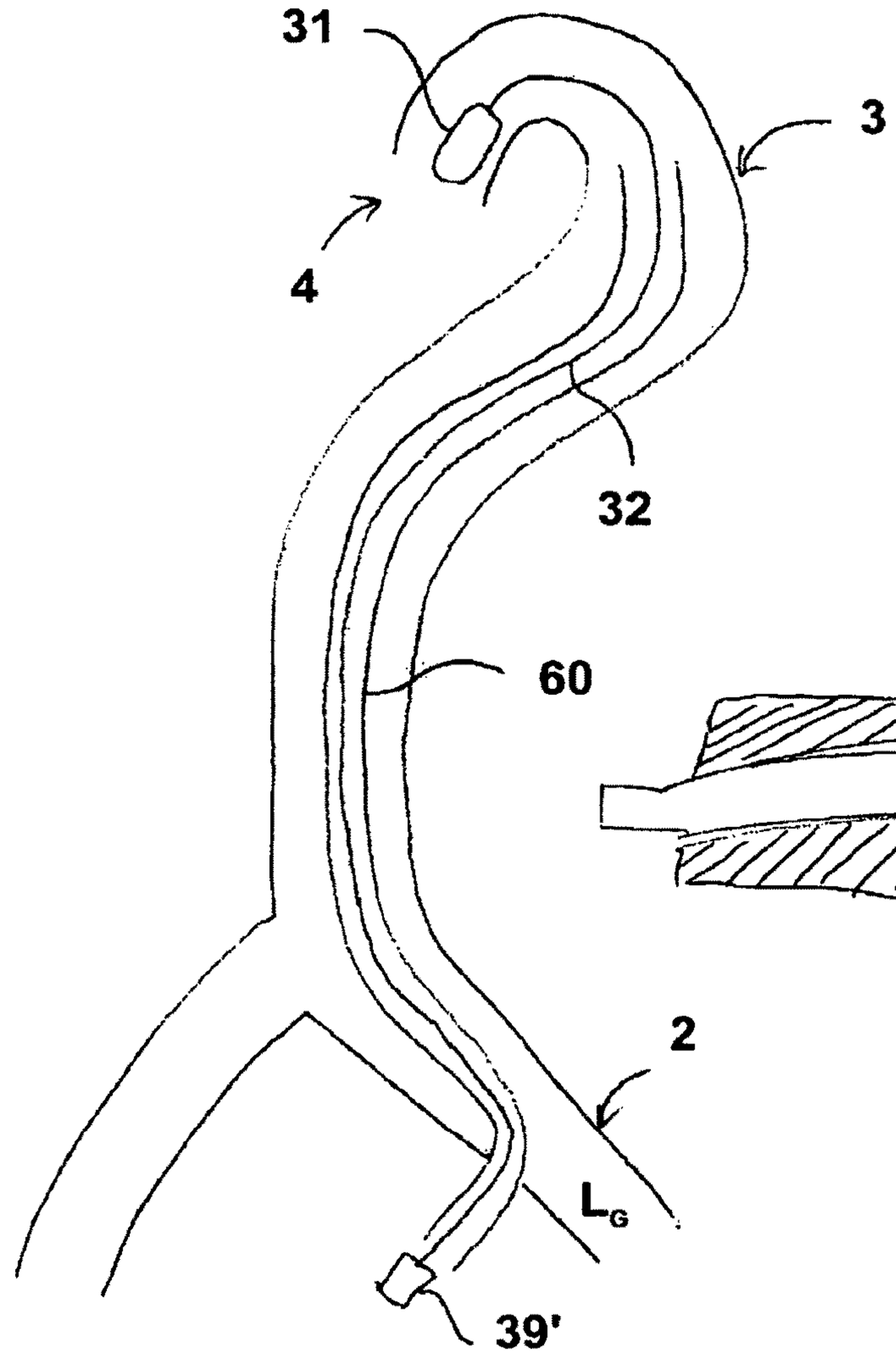


Fig. 14

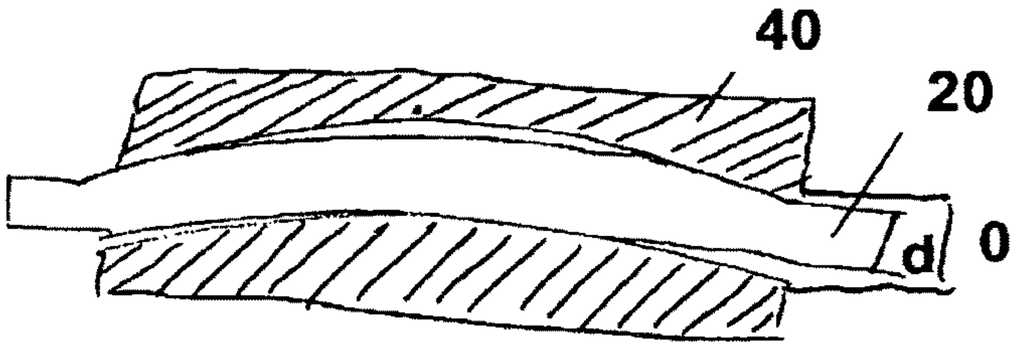


Fig. 15b

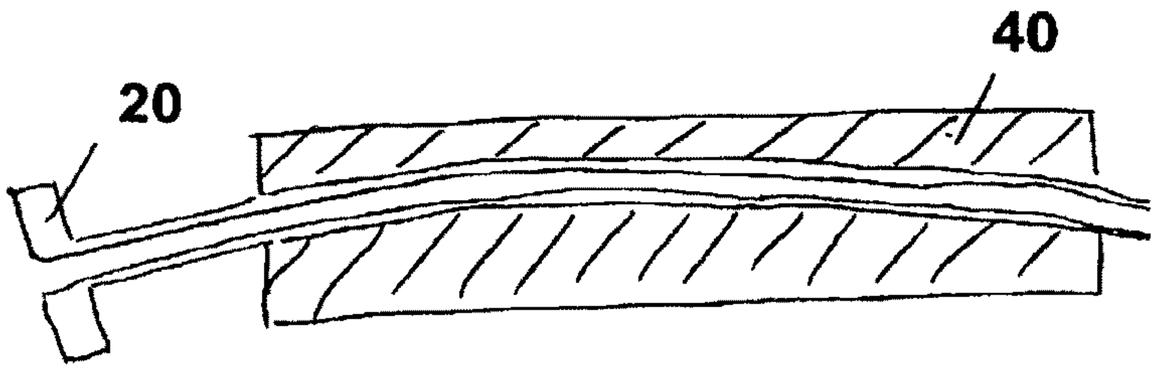


Fig. 15a

# SYSTEM FOR INTRODUCING A PUMP

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 15/956,920, filed Apr. 19, 2018, now U.S. Pat. No. 10,898,625, which is a continuation of Ser. No. 13/261,529, issued as U.S. Pat. No. 9,974,893, filed Nov. 27, 2012, which is a national stage entry of PCT Application PCT/EP2011/003187, filed Jun. 24, 2011, which claims priority to U.S. Patent Application No. 61/358,496, filed on Jun. 25, 2010, and European Patent Application No. 10075277.3, filed Jun. 25, 2010, the contents of all of which are incorporated by reference herein in their entirety. International Application No. PCT/EP2011/003187 was published under PCT Article 21(2) in English.

## BACKGROUND OF THE INVENTION

The invention resides in the field of introducing fluid pumps into a lumen and relates to a system for introducing a pump into a lumen, which comprises a first sheath and a pump to be introduced into the first sheath, or a system which has a pump with a distal pump unit and a shaft catheter which emerges proximally to the pump unit.

The application can hence be provided, on the one hand, in the minimally invasive medical field, for example as a blood pump for heart assistance, and, on the other hand, also use in agitators or as a drive element is conceivable.

The invention can display special advantages by the possible miniaturisation in the medical field. Techniques for introducing fluid pumps, in particular into natural body lumina, are known in detail in prior art. Thus reference is made inter alia to the Seldinger technique for introducing an introducer sheath into a vascular system. The technique and possible variants are intended to be explained in more detail with reference to FIG. **1**.

A schematic human vascular system **1** is shown in FIG. **1**. In the groin region there is one of the femoral arteries **2** which is connected to the aortic arch via a main artery and subsequently opens into the ventricle **4**. With the help for example of the Seldinger technique, firstly an introducer sheath **10** is introduced into the femoral artery **2**. Firstly, the femoral artery or any blood vessel is hereby punctured with a steel cannula with a cutting tip. A guide wire **12** is pushed through the steel cannula introduced into the puncture and is introduced retrogressively via the aortic arch **3** into the left ventricle **4**. After removing the puncturing cannula, the first sheath **10** which is configured as introducer sheath and comprises a tubular portion **11** is threaded onto the guide wire and introduced into the vascular system through the punctured point, the sheath being introduced into the lumen of the vascular system merely by a small distance. Subsequently, a fluid pump is introduced into the vascular system through the introducer sheath **10**.

Such a method is known for example from WO 02/43791 A1. After the introducer sheath, as represented in FIG. **1**, has been introduced into the vascular system, a heart pump is pushed forwards along the guide wire **12** into the left ventricle **4**. The pump, in particular a distal pump unit, is thereby pushed outside the sheath through the vascular system towards the ventricle.

Modern fluid pumps often rotate at high speeds in order to be able to convey a corresponding quantity of fluid per minute. Such a blood pump can be deduced for example from the above-mentioned WO 02/43791 A1 or from EP 2



047 872 A1. The latter shows a pump which has a distal pump unit, a shaft catheter abutting against the proximal end of the distal pump unit, the shaft catheter in turn being able to be connected to a drive unit for driving the fluid pump.

One disadvantage in the previously known systems for introducing a pump into a lumen is the great danger of damaging the shaft extending in the shaft catheter, which has a negative effect on the lifespan or the useful life of the pump unit.

## BRIEF SUMMARY OF THE INVENTION

Starting from the known state of the art, it is the object of the present invention to reduce the danger of damaging the shaft catheter of a pump.

The object is achieved by a system according to the present disclosure. Furthermore, methods for introducing and removing pumps are included by the invention.

Further embodiments are cited in the subordinate and coordinated claims.

A first aspect of the invention is offered by a system for introducing a (preferably expandable) pump (for particular preference self-expandable rotary pump) into a lumen, the system comprising a first sheath and a pump to be introduced into the first sheath and the first sheath having a first sheath lumen which extends from a distal end to a proximal end for introducing the pump.

A self-expanding pump can be decompressed on the basis of being taken out of the sheath since the sheath no longer restricts the radius of the pump. Alternatively, the self-expanding pump can have a material which changes its state on the basis of the flow conditions, the temperature prevailing in the vascular system or the pressure and thus effects decompression of the pump unit taken out of the sheath.

With regard to the details of the pump (according to the aspects of the invention presented in this application), reference is made to the entire disclosures of U.S. Provisional Applications No. 61/120,095, filed on Dec. 5, 2008, No. 61/149,753, filed on Feb. 4, 2009, No. 61/151,964, filed on Feb. 12, 2009, No. 61/161,125, filed on Mar. 18, 2009, No. 61/162,710, filed on Mar. 24, 2009, No. 61/173,666, filed on Apr. 29, 2009, No. 61/175,519, filed on May 5, 2009, No. 61/220,292, filed on Jun. 25, 2009, No. 61/231,787, filed on Aug. 6, 2009, No. 61/244,592, filed on Sep. 22, 2009, No. 61/244,600, filed on Sep. 22, 2009, No. 61/244,608, filed on Sep. 22, 2009, No. 61/244,614, filed on Sep. 22, 2009, No. 61/254,315, filed on Oct. 23, 2009, No. 61/254,339, filed on Oct. 23, 2009, No. 61/289,569, filed on Dec. 23, 2009, No. 61/289,645, filed on Dec. 23, 2009, No. 61/289,656, filed on Dec. 23, 2009, No. 61/293,270, filed on Jan. 8, 2010, No. 61/297,858, filed on Jan. 25, 2010, No. 61/298,581, filed on Jan. 27, 2010, No. 61/310,750, filed on Mar. 5, 2010, No. 61/345,253, filed on May 17, 2010, No. 61/358,496, filed on Jun. 25, 2010, No. 61/364,559, filed on Jul. 15, 2010, No. 61/364,578, filed on Jul. 15, 2010, No. 61/364,595, filed on Jul. 15, 2010, and No. 61/451,222, filed on Mar. 10, 2011, which are hereby incorporated by reference in this application in their entirety.

There is understood by the term sheath in the present application, essentially a lumen which is surrounded by a casing and has a distal and a proximal opening. Preferably, the sheath is configured such that this can receive a shaft catheter, for example a shaft catheter with a diameter of 5-15 Fr, preferably 7-11 Fr. In addition, a sheath is preferably flexible so that this can be guided through a natural body lumen. This applies both to the first and the second sheath.

According to the invention, the system comprises furthermore a second sheath with a second sheath lumen which extends from a distal end to a proximal end and in which the pump is retained in a guidable manner. The second sheath is thereby configured such that it can be coupled to the first sheath for transferring the pump from the second into the first sheath.

The second sheath offers additional protection for the shaft catheter during introduction of the pump. In this way, an improved introduction of the pump into the first sheath or into the first sheath lumen is made possible.

In the sense of the present invention, "sheath" implies an object through which something different can be guided. Such a sheath can, but need not necessarily, have a haemostatic valve.

Since threading the pump into a sheath is associated generally with great care and hence associated with considerable time expenditure, the second sheath makes threading the pump unit into the same possible before the actual transfer of the pump into the lumen which receives the pump. In other words, the pump can be inspected firstly well before an operation and subsequently threaded into the second sheath, preferably pulled in, threading in being able to be undertaken without pressure of time.

At the time of the operation, the second sheath in which the pump is firstly retained must now be coupled merely to the first sheath, and the pump can be transferred directly from the second into the first sheath. This reduces the probability of damaging the pump or the shaft and enables thus an improved running performance or running time of the pump itself. Also, the time expenditure for introducing the pump which is required during for example an operation is reduced.

A second aspect of the invention relates to a system which can be used in the above-mentioned system, having a pump which comprises a distal pump unit and a shaft catheter which emerges proximally to the pump unit. In addition to the pump, the system has furthermore a sheath with a sheath lumen which is disposed proximally to the distal pump unit, the sheath lumen surrounding a portion of the shaft catheter. The feature termed merely sheath is designated in the system of the first aspect of the invention generally as second sheath. Such features relate to the system according to the second aspect.

The sheath is configured such that the sheath can be displaced along the shaft catheter in the direction of the distal pump unit and the distal pump unit can be introduced into the sheath lumen. This presupposes that the inner diameter of the sheath lumen is greater than the outer diameter of the shaft catheter.

In the system consisting of the pump and the sheath, it is advantageous in particular that pulling can take place on the shaft catheter for pulling in the distal pump unit into the distal end of the sheath. Since, when pulling the shaft, the danger of distortions or damage or bending of the shaft relative to pressing in or pushing in the device into a sheath is significantly reduced, the running time or lifespan of the pump unit is improved relative to the conventional methods for introducing the pump and the systems used there.

After the pump has been pulled into the sheath and the distal end of the distal pump unit is situated partially or completely proximally to the distal end of the sheath, the system of the second aspect can be coupled, according to the first aspect of the invention, to a first sheath so that more simple introduction of the pump unit into the lumen which ultimately receives the pump, such as e.g. a blood vessel, is achieved.

According to a third aspect of the invention, the systems of the first or second aspect of the invention can be further improved. The third aspect comprises a device for retaining a portion of the sheath of the second aspect or of the second sheath of the first aspect. The device for retaining the portion of the sheath is thereby configured such that it can retain the sheath frictionally, on the one hand, and on the other hand, prevent deformation, in particular bending, of the sheath in the retained region. Due to the device for retaining a portion of the sheath, a possibly present intrinsic reinforcement of the sheath, for example in the form of a wire mesh, is not required since the retaining device effects reinforcement of a portion of the sheath. This leads to the fact the bending of the shaft when pulling the pump into the lumen of the sheath is not possible and when transferring the pump from the sheath retained by the device into the first sheath is possible but made difficult.

The three aspects described in the preceding paragraphs each form per se an independent patentable part of the invention. Although the third aspect, i.e. the device for retaining a portion of a sheath, has been described merely as an improvement to the system of the second aspect, an independent significance is also attributed to it. The common inventive idea is to introduce the pump into a second sheath before introduction into the lumen which is to receive the pump without pressure of time.

All three aspects are suitable per se for preventing bending of the shaft of a pump.

Further embodiments of the different aspects are subsequently dealt with.

In one embodiment of the first aspect of the invention, the first sheath lumen has, in regions, a smaller inner cross-sectional area, preferably a smaller inner diameter, than the second sheath lumen. This has the advantage that threading the pump into the second sheath can be undertaken in a simplified manner. A ratio between 1:1 and 1:1.2 is possible as a suitable size ratio of the inner cross-sectional area of the first sheath lumen to that of the second sheath lumen.

In a further embodiment of the system of the first aspect, the first sheath comprises a first sheath valve at the proximal end thereof. With the help of the sheath valve, the introducer sheath can firstly be introduced into the lumen receiving the pump and leakage of a fluid out of the pump can be prevented.

The sheath valve is thereby preferably configured such that it has a wider inner cross-section than the sheath lumen. Also a conically tapering shape of the sheath valve is included by the embodiment. The sheath valve thereby tapers from its proximal end to the distal end, i.e. towards that end at which it is connected to the sheath lumen. Alternatively or in combination, the first sheath lumen can be configured such that this widens in the region of connection between the sheath lumen and the sheath valve.

The sheath is configured according to the invention such that the distal end of the second sheath can be introduced at least partially into the first sheath valve and the coupling between the first and second sheath is produced in this way.

In one embodiment of the first and second aspect of the invention, the second sheath is a tear-off sheath or a "peel-away" sheath which can be torn off over its entire length. Sheaths of this type have for example a molecular structure which facilitates tearing off from the proximal end towards the distal end. The tear-off sheath can however also be configured to be able to be torn off for example by a material tapering in the manner of a predetermined breaking point or by a longitudinally inserted tear-off wire or thread. As a result, the second sheath, after the pump has been transferred

from the second sheath into the first sheath, can be torn off and withdrawn from the pump, in particular from the shaft catheter extending therein. The second sheath represents, in this variant, a feature of the invention which is connected to the pump merely before introduction into the lumen which receives the pump.

In a further embodiment of the first and second aspect of the invention, the first and the second sheath comprise a plastic material which can be provided, in a further embodiment, with a strengthening or reinforcing structure. Plastic material represents a particularly suitable material choice in the medical field.

In an embodiment of the third aspect, the device for retaining a portion of the second sheath comprises a cavity in which the portion of the second sheath can be retained frictionally. This can be achieved for example via a roughened surface of the cavity. Another possibility resides in configuring the inner cross-sectional area of the cavity minimally less than the outer cross-sectional area of the second sheath. As a result of the fact that the device has a cavity, the surfaces surrounding the cavity can serve as retaining surface for an operator of the system. Also as a result, damage to the shaft is avoided. There is possible as material, for example, metal or even a plastic material in order to avoid the transmission of pathogens from the device to the sheath. In the case of use in a human or animal body, preferably biocompatible materials should be used.

In a further embodiment of the third aspect, the device is configured such that the second sheath can be received, over preferably at least half of its length, by the device for retaining the second sheath.

In a further embodiment, the device is configured such that the retained portion of the second sheath comprises a curvature of less than 10°, preferably less than 5°, particularly preferred less than 1°. Due to a curvature of the second sheath, the danger of the shaft bending increases. This can be avoided by a corresponding configuration of the device for retaining a portion of the second sheath.

By means of a curvature of the receiving region of the second sheath on the device, the second sheath is fixed axially without restricting the lumen $L_2$ of the second sheath. For this purpose, the $2^{nd}$ sheath should have an appropriate bending resistance. Alternatively, the $2^{nd}$ sheath can also have a curvature and the device can be straight (or both curved).

For this purpose, a system according to the invention provides that the deviations from the straightness of the second sheath in the clamped region and of the device for retaining a portion of the second sheath are together greater than the difference of the inner diameter of the device for retaining a portion of the second sheath and of the outer diameter of the second sheath, see FIGS. **15***a* and **15***b*.

The system according to the first aspect can be used in conjunction with a system according to the second aspect such that firstly the first sheath is introduced into the lumen which subsequently receives the pump such that the proximal end of the first sheath is accessible outside the receiving lumen. Before or thereafter, the distal end of the pump can be moved into the sheath lumen of the second sheath, preferably can be pulled into the second sheath with the help of a system according to the second aspect.

For this purpose, the second sheath can be reinforced at least axially in the distal region thereof. Hence bending of the pump or of the second sheath when pulling the pump into the sheath can be prevented.

Subsequently, the distal end of the second sheath is coupled to the proximal end of the first sheath and the pump is transferred from the second sheath into the first sheath.

In one embodiment, the distal end of the pump is subsequently guided through the distal end of the first sheath lumen into the lumen which receives the pump.

In one method for designing the pump, the distal pump unit which is placed distally to the distal end of the sheath remaining in the vascular system is pulled into the sheath and subsequently removed from the receiving lumen through the sheath. Alternatively, the pump can be removed together with the receiving lumen.

In one embodiment of the method for designing the pump, the distal end of the sheath is situated during the operating state of the pump unit less than 20 cm, preferably less than 10 cm, away from the operating location of the pump unit. As a result, transport of the pump unit to the operating location and away from this is simplified. Furthermore, the vascular system is hereby protected from lesions by the pump (during transport of the same).

The present patent application relates in addition to a catheter pump, which can be introduced into human or animal vessels in a compressed state and can be operated in an expanded state in a lumen of the human or animal body in order to convey a fluid, the catheter pump having a rotor for conveying fluid, a housing which surrounds the rotor and is at least partially fluid-permeable and also an introducer sheath close to the rotor, wherein, during transfer from the expanded state into the compressed state, the housing can be introduced into the introducer sheath for narrowing of the diameter at least in regions, and this narrowing of the diameter of the housing is dimensioned such that also the diameter (i.e. the largest outer diameter) of the rotor is reduced by the narrowing of the diameter of the housing from the expanded state to the compressed state.

The invention described in the preceding paragraph is per se for catheter pumps an independent invention so that the applicant reserves the right to direct a separate partial application thereto subsequently.

Advantageous developments of this catheter pump (see previous paragraph) can be detected from the originally filed FIGS. **1** to **15***b*, in particular from FIG. **4**, **5** or **6**.

All the embodiments or originally filed patent claims mentioned here, provided that this is not technically contradictory, should be valid as possible developments.

The basic principle of an embodiment of a catheter pump of the present disclosure is based on the fact (this applying of course to all aspects of the application) that the introducer sheath itself does not compress the rotor but that this takes place directly by means of a housing surrounding the rotor. In other words, a fixed spatial arrangement exists between the rotor and the housing surrounding the rotor, i.e. the rotor is not moved independently of the surrounding housing. The fixed spatial arrangement may be understood as the proximal or distal end of the rotor being fixed with respect to at least one location of the surrounding housing. This housing can (as shown in this application) have a grid structure which is closed in regions. As a result, suction of fluid into the housing is possible and conveyance to the proximal end of the catheter is possible. The mentioned rotor can have various forms, for example it can have different rotor blades, these individual rotor blades being also able to have lamellae. The rotor can also have an outer plastic material surface and be configured for example as a plastic material cast or injection moulded part. It is important that the rotor can also have a compressed state for introduction into the vessel (or the housing/the sheath) and also an expanded state in which

a conveying operation is possible and in which the rotor is protected by the surrounding housing. A gap between the radial rotor outer edges and the housing can hereby exist. Even during operation the housing can be disposed still in regions in the introducer sheath close to the rotor as long as free rotation of the rotor is not impeded as a result.

Furthermore, the shaft can be coupled to the motor by means of a magnetic coupling.

The above-mentioned inventions are therefore suitable in particular for self-decompressible pumps.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention is intended to be explained subsequently in more detail with reference to a few embodiments. There are shown:

FIG. **1** a schematic overview of a vascular system with an introduced first sheath;

FIG. **2** a detailed view of a cut-out of FIG. **1**;

FIG. **3** an embodiment of a system according to the first aspect of the invention;

FIG. **4** an embodiment of a pump;

FIG. **5** an embodiment of a system according to the second aspect of the invention;

FIGS. **6**, **7** pulling a pump into a second sheath;

FIGS. **8**, **9** transfer of a pump from a second into a first sheath;

FIG. **10** an embodiment of the system according to the second aspect with a device according to the third aspect of the invention;

FIG. **11** a cross-section of the representation of FIG. **10**;

FIG. **12** an embodiment according to the first and third aspect of the invention;

FIGS. **13***a* and **13***b* an embodiment of a distal end of a sheath according to the second aspect of the invention;

FIG. **14** an embodiment of a long sheath and the arrangement thereof during the operating state of the pump unit;

FIGS. **15***a* and **15***b* sketches for clarification of curves.

## DETAILED DESCRIPTION OF THE INVENTION

As already mentioned initially, FIG. **1** shows a schematic representation of a human vascular system in which a first sheath **10** configured as an introducer sheath has been introduced into the femoral artery with application of the Seldinger technique.

In FIG. **1**, a guide wire **12** which extends into to the left ventricle is shown furthermore. The tubular portion **11** of the first sheath **10** is introduced into the artery such that the proximal end of the first sheath **10** is situated outside the femoral artery and hence can be used to introduce for example a pump. On the one hand, it is possible to thread the pump onto the guide wire **12** in order to guide the pump into the left heart ventricle by means of the guide wire.

It is a method according to the invention to guide the tubular portion **11** of the first sheath **10**, guided by the guide wire, into the left ventricle and subsequently to remove the guide wire **12** from the first sheath. A possible pump unit is subsequently guided through the first sheath lumen into the vicinity of or into the left ventricle **4**.

The invention is presently represented merely with reference to introduction of a pump into the left ventricle for assisting a heart function. However, it can be detected easily by the person skilled in the art that the pump can be disposed also at other positions in the natural body vascular system. Furthermore, it is evident to the person skilled in the art that the invention is not restricted exclusively to the natural body vascular system but is suitable for introduction of a pump into any lumina. This includes for example lumina which are defined by tubes, into which a pump unit is intended to be introduced for conveying a flow.

In FIG. **2**, the region of FIG. **1** in which the first sheath **10** is guided through the natural body tissue from outside into the lumen LG of the femoral artery **2** is represented. The first sheath thereby comprises a tubular portion **11** which is connected proximally to a valve **13**. The tubular portion **11** defines a lumen $L_1$ which has an inner diameter dn. The latter widens in the manner of a trumpet towards the proximal end of the tubular portion **11**. The trumpet-like widening **14** leads to the diameter of the valve **13** being greater than the inner diameter $d_{11}$.

The valve **13** concerns a haemostatic valve which is known in prior art and comprises a housing **15** and a gasket **16**. The haemostatic valve prevents fluid situated in the lumen $L_G$ from emerging outwards through the lumen $L_1$.

In the illustration of FIG. **3**, the first sheath **10** of FIG. **2** is coupled to a second sheath **20**. Merely a tubular portion **21** of the second sheath **20** which defines a lumen $L_2$ with an inner diameter $d_{21}$ is shown. The distal end of the second sheath **20** which is coupled to the valve **13** thereby has such an outer diameter that it can be introduced into the valve **13**. The inner diameter $d_{21}$ is however greater than the inner diameter $d_{11}$.

At this point, reference may be made to the fact that the position of the valve is not restricted to the proximal end of the first sheath but can also be disposed at other positions inside the first sheath, such as for example the distal end of the first sheath or in the centre. It is sufficient for introducing the distal end of the second sheath into the proximal end of the first sheath if the proximal end of the first sheath has an inner diameter which is greater than the outer diameter of the distal end of the second sheath. The diameter of the lumen of the first and second sheath (apart from the proximal end of the first sheath and the distal end of the second sheath) can be uniform or different or the lumen of the respective sheath can be tapered.

The first and second sheath and also the distal pump unit are configured such that the distal pump unit can come to be situated in the first and second sheath, whilst the proximal end of the second sheath is situated in the distal end of the first sheath or is coupled thereto.

A pump situated in the lumen $L_2$, not illustrated, can now be transferred from the second sheath lumen $L_2$ into the first sheath lumen $L_1$ by pressing. Subsequently, the pump is transported through the first sheath lumen $L_1$ to the position in the vascular system at which the pump is intended to develop its action. The pump can either be guided on a guide wire or be introduced without a guide wire through the first sheath lumen.

A possible embodiment of a pump **30** is explained in more detail with reference to FIG. **4**. The pump **30** comprises a distal pump unit **31** and a shaft catheter **32** which abuts against the proximal end of the distal pump unit **31**. At its proximal end, not illustrated, the shaft catheter **32** has a coupling for coupling the shaft catheter **32** to a drive device. The drive device sets a flexible shaft which extends in the shaft catheter **32** in rotation, which shaft in turn actuates the distal pump unit **31**.

The distal pump unit comprises a pump housing **33** which is produced from intersecting nitinol struts. The nitinol housing is provided in parts with a coating **34** which extends distally and proximally to a rotor **35** disposed in the housing **33**. The rotor is connected to the shaft **36** which extends

through the shaft catheter **32** and is thus set in rotation. The housing and the rotor are compressible, i.e. the pump is a self-decompressible pump. The unfolding of the pump is performed after the distal pump unit is pushed out of the distal end of one sheath. For compression of the pump, the distal pump unit is pulled into the distal end of a sheath lumen. The sheath lumen thereby has an inner diameter which is at least greater than the outer diameter of the shaft catheter.

The distal pump unit is constructed such that the housing surrounding the pump is essentially fixed in the axial direction relative to the rotor, i.e. the rotor is not removed from the housing during the implantation but remains in the same.

Optionally, the pump has a discharge hose **37** which defines a flow channel for the pumped fluid, situated proximally to the rotor **35**. At the proximal end of the discharge hose **37**, outlet openings which are not illustrated in more detail are situated.

Of course, the pump can also be switched from a pumping operation to a suction operation so that the pump no longer conducts fluid from the distal end to the proximal end, but vice versa.

A detailed description of a further suitable pump can be deduced for example from the publication EP 2 047 872 A1.

The function of the system according to the second aspect is now intended to be explained with reference to FIGS. **5** to **9**.

In FIG. **5**, a pump **30'** which corresponds essentially to the pump **30** according to FIG. **4** is represented. For simplification, details of the pump are not shown. Merely the bulbous housing and also the "pigtail" situated distally to the bulbous housing are represented, which housing prevents suction of the heart pump against the heart wall. The shaft catheter **32'** extends proximally to the distal pump unit **3**. Surrounding a region **38'** of the shaft catheter **32'**, a second sheath **20'** is disposed, which comprises a lumen $L_2$, the inner diameter $d_{21}$ of which is less than the diameter of the distal pump unit **3** in the decompressed or unfolded state.

The pump **30'** illustrated in FIG. **5** is a compressible pump, i.e. the distal pump unit **3**Γ which comprises inter alia the pump housing and the rotor situated therein is configured such that it can be compressed, i.e. reduced in its diameter. After a quality tester or for example a doctor has been able to convince himself of the correct function of the pump **30'**, e.g. by observing the rotational movement of the rotor unit situated in the distal pump unit **31'** during a test run, the distal pump unit **31'** is pulled into the lumen $L_2$ of the second sheath **20'** by pulling the shaft catheter **32'** in the proximal direction. By pulling the pump into the second sheath **20'**, bending or damage to the shaft catheter or the shaft extending therein is avoided. The pump **30'** illustrated in FIG. **5** and the second sheath **20'** surrounding the region **38'** of the shaft catheter **32'** form a system **200** which makes it possible to test the function of the pump **30'** well before an operation and subsequently to compress the pump by pulling the distal pump unit **3** into the distal end of the second sheath **20'** and thereby to avoid damage to the shaft.

Although the system according to the first and second aspect can be produced both with actively decompressible pumps and with self-decompressible pumps, it is suitable in particular for self-decompressible pumps, i.e. pumps, the distal pump unit of which outside the sheath automatically assumes the original size again.

In FIG. **6**, an intermediate step when pulling the distal pump unit **3** into the lumen $L_2$ of the second sheath **20'** is represented. It is detectable that the distal pump **3** is compressible and can be brought to a smaller diameter, so that the distal pump unit **3** can be received in the lumen $L_2$ of the second sheath **20'**.

Furthermore, a coupling **39'** which abuts against the shaft catheter **32'** is represented in FIG. **6**, which coupling enables coupling of the shaft extending in the shaft catheter to a drive unit. Since the coupling **39'** has an often larger outer diameter than the inner diameter of the lumen $L_2$, the second sheath **20'** is generally put on in the distal direction before assembly of the coupling **39'** from the proximal end of the shaft catheter **32'** so that the pump in system **200**, i.e. the pump with the second sheath **20'** situated proximally to the distal pump unit **3** and the premounted coupling **39'**, is delivered. In FIG. **6**, a slight trumpetlike widening of the distal end of the second sheath **20'** is represented. The trumpet-like widening **24'** facilitates pulling the distal pump unit **3** into the lumen $L_2$ of the second sheath **20'**.

In FIG. **7**, the distal pump unit **3** is finally situated completely in the lumen $L_2$ of the second sheath **20"**. The second sheath **20"** differs from the sheath **20'** merely by two premounted gripping units **22"** which enable better holding or removal of the second sheath **20"** when pulling the distal pump unit **3** into the lumen $L_2$ or subsequent tearing off. Advantageously, in the case of a "pigtail" being present, this is likewise pulled into the lumen $L_2$ so that the distal pump unit **3** together with components of the pump situated distally to the distal pump unit **31'** is situated in the lumen $L_2$.

In FIG. **8**, it can be detected how the system **200** comprising pump **30'** and second sheath **20"** is combined in operating connection with the first sheath **10** to form a system **100** according to the first aspect of the invention. Firstly, the second sheath **20"** is introduced by its distal end into the valve of the first sheath **10**. As soon as the distal tip of the second sheath **20"** abuts against the trumpet-like widening **14** of the first sheath **10**, by pushing the pump in the distal direction, the pushing being effected by means of pushing the shaft catheter **32'**, the pump is transferred from the second sheath **20'** into the first sheath **10'**. The diameter of the distal pump unit **3** is hereby reduced further to the inner diameter $d_{11}$ of the lumen $L_1$.

In FIG. **9**, the subsequent step in which the distal pump unit **3** is situated completely in the lumen $L_1$ of the first sheath **10** is represented. The fact that the distal pump unit **3** is situated completely in the lumen $L_1$ of the first sheath **10**, can be identified for example with reference to a colour marking **50** which is applied on the outside of the shaft catheter **32'**.

Subsequently, the second sheath **20"**, which is configured as a "peel-away" sheath, is removed from the shaft catheter **32'** by tearing off the peel-away sheath from the proximal towards the distal end and pulling it off the shaft catheter **32'**. The directed tearing off from the proximal to the distal end can be assisted by notches A but is based predominantly on the orientation of the molecular chains of the plastic material which is used from the proximal to the distal direction.

After the peel-away sheath has been removed, the pump **30'** is guided again inside the lumen $L_1$ of the first sheath **10** up to the desired position.

Reinforcement of the second sheath **20"** is unnecessary, in particular when pulling the distal pump unit **3** into the distal end of the second sheath lumen $L_2$ since the danger of bending of the shaft during a pulling movement is greatly reduced.

During transfer of the pump from the second sheath into the first sheath, as illustrated with reference to FIGS. **7** to **9**, the second sheath can include a structure which reinforces it

in the form of an introduced wire, or the tubular portion **21"** of the sheath **20"** is not produced from a flexible plastic material but from a fixed-shape plastic material or metal.

A further possibility for pulling the pump into the second sheath, when moving forwards in the pump **30'** in the distal direction, i.e. in particular when transferring the pump **30'** from the second sheath into the first sheath, resides in retaining the second sheath **20"** by means of a device **40** for retaining the second sheath.

The device for retaining a portion of the second sheath **20"** is represented in cross-section in FIG. **11**. The device **40** has an upper and a lower half **41** or **42** which are connected to each other via a hinge **43**. In the first or second half **41** or **42** there is situated respectively a recess, the recesses in the illustrated, closed state of the device **40** defining a cavity **44**. The cavity **44** configured as a lumen is configured furthermore such that a second sheath **20** can be retained frictionally in the cavity. This can be achieved either via correspondingly chosen inner diameters of the cavity **44** or outer diameters of the second sheath **20** or rough surfaces in the region of the cavity **44**. Also knobs in the region of the cavity **44** can produce a frictional fit.

As can be detected with reference to FIG. **10**, the cavity **44** extends without curvature and hence does not allow any bending of the shaft which extends in the shaft catheter **32'** if the latter is pushed forwards in the distal direction by means of a transverse force. In addition, the device **40** makes an improved grip possible for an operator of the system **200'** for introducing the pump.

In FIG. **12**, the device **40** with the cavity **44** in which a second sheath **20** is retained is represented. The distal end of the device **40** thereby lies on the proximal end of the valve **13** of the first sheath **10**. In the case of such a coupling between the first sheath **10** and the second sheath **20**, simplified introduction of a pump from the second into the first sheath can be achieved.

In FIG. **13***a*, a distal end **22** of an embodiment of the sheath **20**, according to the second aspect of the invention is represented. The distal end **22** has an internal and external tapering of the edge **23** surrounding the lumen L, as a result of which an improved introduction of the sheath into the natural body lumen or a first sheath according to the first aspect of the invention is possible. Likewise, the distal end **22** can be the end of second sheath according to the first aspect of the invention. A possible proximal end can have the same shape of configuration.

FIG. **13***b* shows a further variant; an additional feature hereby is that the distal end has such a flexible or elastic configuration that it widens slightly when pulling in the pump head and consequently facilitates insertion. After complete insertion of the pump head, the distal end again adopts extensively the original shape. During introduction of the distal end of the second sheath into the first sheath, the distal end of the second sheath can also be fitted by the elastic/flexible tapering to the proximal end of the first sheath and consequently can facilitate coupling.

The systems, represented in the present documents, according to the first, second and third aspect hence enable simplified handling and improved introduction of pumps into a lumen.

Subsequently, another possible variant of a method for introducing a pump into a left ventricle is intended to be portrayed. As a preparatory measure, the pump is firstly filled with sterile physiological common salt solution and hence completely deaired. Subsequently, the peel-away sheath placed proximally to the distal pump unit is pushed forwards up to a possibly present discharge hose. The peel-away sheath has a diameter of approx. 10 Fr. After the peel-way sheath has been pushed forwards up to the discharge hose, the peel-away sheath is surrounded by the device for retaining the second sheath. Subsequently, the distal pump unit, possibly with a slight rotational movement is pulled into the peel-away sheath by exerting a pulling movement on the shaft catheter in the proximal direction. The pump is displaced into the second sheath until a possibly present pigtail is likewise hidden in the peel-away sheath. By means of these steps, it is possible to test the functional capability of the pump even before an operational procedure and to introduce the pump only subsequently into a sheath without requiring to act under pressure of time. For example, the puncturing of the vascular system for introducing the first sheath is only implemented subsequently. In order to save time, it is however also possible in this way that an assistant prepares the pump whilst the user already implements the puncturing in parallel.

After for example a 9 Fr introducer sheath has been introduced into the left ventricle, a possibly present dilator is pulled out of the introducer sheath and removed therefrom.

Subsequently, the pump retained in the peel-away sheath, which is surrounded for example by the device for retaining the second sheath, for example a 2 cm long portion of the distal end of the peel-away sheath protruding at the distal end of the device, is coupled to the haemostatic valve of the introducer sheath until the tip of the peel-away sheath abuts inside the introducer sheath. Subsequently, the pump is transferred from the peel-away sheath into the introducer sheath by pushing the shaft catheter.

As soon as the distal pump unit has been transferred completely into the introducer sheath, as can be checked for example with reference to an optical marking on the shaft catheter shaft, the device for retaining the second sheath can be removed from the second sheath and the peel-away sheath can be torn off and withdrawn from the shaft catheter. Subsequently, the pump is pushed forwards inside the introducer sheath up to the left ventricle. The introducer sheath is subsequently pulled back from the left ventricle up to the beginning of the descending aorta.

The positioning of the distal pump unit in the left ventricle can be checked for example by radioscopy. For this purpose, an X-ray-visible marking is situated on the pump housing or the pump housing itself is X-ray-visible. Likewise, the outlet region, i.e. the outflow openings of a discharge hose, should be situated in the region of the ascending aorta. This can also be checked with an X-ray-visible marking. A possibly present pigtail catheter tip should abut against the tip of the left ventricle.

In order to remove the pump from the ventricle, this is pulled back into the introducer sheath by means of a tensile force applied on the shaft catheter and is removed, in a compressed state, from the arterial vascular system. Subsequently, the introducer sheath and further remaining components are removed from the vascular system.

A further aspect of the invention is the use of a long sheath during implantation and explantation of the pump. The long sheath serves not only, as is common in prior art, for introducing the pump into a natural body lumen but for guiding the pump through the sheath lumen to the vicinity of the operating location. It is hereby advantageous if, in the medical field, the sheath has a length between 40 and 120 cm. The length is generally determined by the subsequent operating location of the pump and the physical constitution of the patient. The long sheath can be provided, on the one hand, by the first sheath of the system according to the first

aspect of the invention and, on the other hand, by the sheath of a system according to the second aspect of the invention. A schematic representation of a long sheath and of the distal pump unit in the operating state can be deduced from FIG. **14**.

The long sheath **60**, which is formed by a first or second sheath of the system according to the first aspect of the invention or a sheath of the system according to the second aspect of the invention, ends at the aortic arch **3**, the shaft catheter **32** of the pump **30** extending through the lumen of the long sheath and emerging at the distal end of the sheath lumen. The distal pump unit **31** is located in the ventricle **4** in the operating state.

Alternatively, the length of the long sheath can be chosen such that this ends in the ventricle before decompression of the pump so that the distal pump unit is unfolded only in the ventricle.

At the proximal end of the long sheath, the coupling **39'** is situated, which serves for coupling the shaft which extends in the shaft catheter to a drive unit.

The long sheath has such a length that it is possible to place the distal pump unit in the vicinity of the operating location.

Essentially two functions are attributed to the long sheath. One the one hand, the long sheath enables guidance of the pump to the operating location. Since the pump is compressed in the sheath lumen of the long sheath, conveyance of the pump to the place of use, relative to sole guidance by a guide wire, is simplified. In addition, this serves for avoiding complications or injury to the inner vascular walls. In particular in the case self-unfolding pumps, i.e. pumps which have no active actuatable components for unfolding the distal pump unit, this is a significant simplification relative to guidance of the pump unit by means of a guide wire. On the other hand, the long sheath enables simplified explantation of the pump. The pump unit, after completion of the conveying performance, is pulled into the distal end of the long sheath by a pulling movement of the shaft catheter, consequently compressed and subsequently withdrawn either through the sheath lumen of the long sheath or pulled, together with the long sheath, out of the natural body lumen.

If the pump is withdrawn together with long sheath out of the natural body lumen, bleeding of the femoral artery is stopped with a pressure bandage. Alternatively, the pump can be withdrawn from the sheath lumen of the long sheath. Then a further guide wire can be placed through the lumen of the sheath, via which then, after removal of the sheath, a device for closing the puncture can be guided. As a result, improved stoppage of the bleeding can be achieved.

If the first sheath of the system according to the first aspect of the invention is configured as a long sheath, a system according to the second aspect can be introduced into the proximal end of the long sheath. Subsequently, the second sheath is possibly withdrawn from the shaft catheter and the pump is guided through the sheath lumen of the long sheath to the operating location of the pump.

As an alternative hereto, the long sheath can also be formed by a sheath in the sense of the system of the second aspect of the invention. A first sheath, in the sense of the first aspect, can then be dispensed with. In this variant, the distal pump unit of the pump is firstly pulled into the distal end of the sheath lumen of the sheath according to the second aspect of the invention. Subsequently, the sheath in the sense of the second aspect is transferred for example with the help of the Seldinger technique into the natural body lumen. The sheath is then pushed into the vicinity of the operating location of the pump. The pushing is thereby effected preferably on the outside of the sheath. In order to be able to apply this method, the pump is guided via a guide wire. This can be guided for example by a guide wire lumen of the catheter tip or an additional lumen of the sheath.

Conveyance of the pump to the operating location is possible in different ways. After the sheath is situated with its distal end in a natural body lumen, the pump can be guided to the operating location by pushing the shaft catheter out of the sheath and outside the latter. It must hereby be ensured that the pump unit must be pushed in the unfolded state through the natural body vessel on the basis of the absence of compression force of the sheath lumen. In this variant, a long sheath is not required.

Although a possible alternative for guiding the pump unit to the operating location is present in the above-described variant, it is preferred to guide the pump in the folded or compressed state inside the sheath lumen to the vicinity of the operating location. For guidance of the sheath inside the vascular system, a rapid-exchange technique can be used, on the one hand, a guide wire being coupled for example to a possibly present catheter tip and the sheath being pushed along the guide wire. Alternatively, the sheath can include a further sheath lumen for receiving a guide wire, the sheath being pressed forwards towards the guide wire.

After the distal pump unit has been pushed out of the distal end of the sheath lumen, the pump is displaced forwards merely by a small distance. The small distance in the case of the human heart as operating location of the pump is less than 20 cm. In the ratio to the total length of the long sheath, a small distance is defined by a ratio of the total length to the small distance of 3:1 or more.

The sheath can remain for the period of treatment in the natural body vascular system—surrounding the shaft catheter. In this case, the pump can be pulled into the distal end of the sheath for explantation and subsequently, as described in one of the preceding paragraphs, be removed from the natural body vascular system.

Alternatively, if the long sheath concerns a tear-off sheath, this can be withdrawn and removed after guiding the pump to the operating location. An explantation of the pump is then no longer possible by means of the sheath. An additional tool is required which enables the explantation of the pump and forms an independently patentable subject of the invention.

The additional tool is only introduced into the vascular system at the time of the explantation. The additional tool has a lumen for introducing the distal pump unit. During introduction of the additional tool, it must be ensured that no non-sterile regions of the shaft catheter are crossed. By crossing non-sterile regions, germs can be introduced into the vascular system. In order to achieve a germ-free introduction of the additional tool, it is possible to pull a portion of the shaft catheter situated in the vascular system out of the lumen since the portion formerly situated in the vessel normally has no foreign germs. The non-sterile region of the shaft catheter which lies outside the patient during use of the pump and which extends up to the drive coupling is removed for example by cutting off. The shaft catheter can also have a suitable predetermined breaking point. In this case, the additional tool can have a tubular or hose-shaped configuration and can be guided directly via the severed catheter end. A possible handle would facilitate handling.

The lumen of the additional tool has an inner diameter which corresponds essentially to the outer diameter of the catheter to be explanted or to the outer diameter of the again compressed pump head. During separation of the non-sterile

regions of the shaft catheter, it must hence be ensured that only components of the pump which can be inserted into such a created lumen remain distally to the distal end of the additional tool.

Alternatively, the additional tool can be configured in the form of a longitudinally divisible tube. In this case, separation of the non-sterile catheter region would be unnecessary since the tool can also be placed directly on the withdrawn region.

In the preceding examples, the system according to the second aspect of the invention was described such that, when the system is delivered, the sheath is situated proximally to the distal pump unit and the distal pump unit is pulled by the user of the pump into the distal end of the sheath lumen of the sheath. This has the advantage that the user can test the functional efficiency of the pump in advance. Alternatively, the system can also be delivered even already with an inserted distal pump unit. The test run of the pump then takes place at the workplace.

If the pump is a self-decompressible pump, the second sheath of the system, according to the first aspect of the invention, which serves inter alia for compression of the distal pump unit, can be replaced, in a variant of the system according to the first aspect of the invention, by a crimping tool.

The crimping tool has, at its distal end which is coupled to the proximal end of the first sheath, for example a diaphragm which effects compression of the distal pump unit of the pump when the distal pump unit is intended to be transferred into the first sheath. The diaphragm can be part of a funnel-shaped tapering, the diaphragm being situated at the distal end of the tapering.

If a crimping tool is used, the distal pump unit is transferred by pushing into the first sheath of the system according to the first aspect of the invention.

In summary, the systems according to the first, second and third aspect form independent inventions. Further variants of the invention are provided by a system according to the second aspect with a long sheath, a system according to the first aspect with a long first sheath, a system according to the first aspect with a long second sheath, a system according to the first aspect with a crimping tool, possibly instead of a second sheath. The corresponding embodiments of the system according to the first, second and third aspect can be applied likewise to the further variants of the invention.

The presented treatment methods are likewise included by the invention. This relates in particular to the implantation and/or explantation of the pump by means of a long sheath.

Also the variants of the invention cited in the preceding paragraph are suitable for implantation and/or explantation, as described in the present application.

The invention claimed is:

**1**. A system for introducing a blood pump into a lumen of a patient's body, the system comprising:

a first sheath having a first sheath distal end and a first sheath proximal end, the first sheath forming a first sheath lumen, the first sheath distal end configured to be positioned in the lumen of the patient's body;

a second sheath having a second sheath distal end and a second sheath proximal end, the second sheath forming a second sheath lumen, the second sheath coupled at the second sheath distal end to the first sheath proximal end thereby forming a blood pump passage from the first sheath to the second sheath;

a first sheath valve coupled to the first sheath proximal end; and

a housing at least partially surrounding the second sheath, the housing comprising a cavity sized to retain at least a portion of the second sheath, the cavity having a longitudinal degree of curvature.

**2**. The system of claim **1**, wherein the first sheath valve is positioned outside the housing.

**3**. The system of claim **1**, wherein a distal end of the housing is positioned proximate a proximal end of the first sheath valve.

**4**. The system of claim **1**, wherein the housing is not surrounding the first sheath.

**5**. The system of claim **1**, wherein the cavity is configured to have a longitudinal degree of curvature of less than 10 degrees.

**6**. The system of claim **1**, wherein the second sheath is a tear-off sheath which can be torn off.

**7**. The system of claim **1**, wherein the first sheath valve is a hemostatic valve.

**8**. The system of claim **7**, wherein the first sheath valve comprises a first sheath valve housing and a gasket.

**9**. The system of claim **1**, wherein the second sheath distal end is configured to couple to the first sheath valve.

**10**. The system of claim **1**, wherein the second sheath distal end is configured to be introduced into the first sheath valve.

**11**. The system of claim **10**, wherein an outer diameter of the second sheath distal end is less than an inner diameter of the first sheath valve.

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